Message Text

UNCLASSIFIED

PAGE 01 STATE 131573

67
ORIGIN HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 MED-03 /025 R

66619
DRAFTED BY DHEW/FDA/JRWEIEROTH M D
APPROVED BY OES/SCI/BMP MBEAAUBIEN
DHEW/OIH/MACODDING
EA/J CDUNKERLEY (INFO)
                     --------------------   065854
P 052116Z JUN 75
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 131573

E.O. 11652: N/A

TAGS: OGEN TBIO JA

SUBJECT FDA REPRESENTATIVE MAKING SITE VISIT

REF: A3214; STATE 103521

1. FDA ADVISES THAT MR. CHARLES A. WAYNE, OFFICE OF THE EXECUTIVE
DIRECTOR OF REGIONAL OPERATONS (VEDRO), WHILE IN JAPAN PROVIDING
TECHNICAL ASSISTANCE TO PHARMACEUTICAL FIRMS, PLANS TO VISIT
SCIENCE COUNSELOR OF EMBASSY ON MONDAY JUNE 9, 1975 AT
10 A. M. (LOCAL TIME) TO DISCUSS HIS PROPOSED SITE VISIT TO DR.
MARUYAMA'S CLINIC.

2. MR. WAYNE HAS BEEN BRIEFED BY REPRESENTATIVES OF EDRO,
BUREAU OF BIOLOGICS, AND BUREAU OF DRUGS CONCERNING FDA'S POLICY WITH
REGARD TO THE MARUYAMA VACCINE. MR. WAYNE HAS AN APPOINTMENT TO
MEET WITH DR. MARUYAMA ON TUESDAY JUNE 10, 1975 AT 3P.M. LOCAL
TIME. AT THIS TIME HE WILL CONDUCT AN INSPECTION OF THE FACILITIES,
WITH THE INTENTION OF ASCERTAINING DETAILS OF MANUFACTURING
PROCESS AND FACILITIES TO ASSURE THAT THIS VACCINE IS MADE IN
ACCORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICE (GMP) REGULATIONS
.
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 131573

THIS INFORMATION WILL PROVE MOST USEFUL TO THE BUREAU OF
BIOLOGICS WHICH HAS CURRENTLY 9 ACTIVE INVESTIGATIONAL NEW
DRUGS FOR THIS VACCINE AND IS BEING PRESSURED TO APPROVE OTHERS
WHILE AT THE SAME TIME, THE BUREAU FINDS THAT BASIC DATA
ORDINARILY REQUIRED FOR PERMITTING AN INVESTIGATION OF A NEW
VACCINE IS LACKING.

3. MR WAYNE WILL REQUIRE THE SERVICES OF AN INTERPRETER AS
DR. MARUYAMA DOES NOT APPARENTLY SPAK ENGLISH. HE ALSO WISHES
TO CABLE THE RESULTS OF HIS FINDINGS TO FDA VIA THE EMBASSY'S
FACILITIES. HE PLANS TO DO SO ON JUNE 11, 1975. COPIES OF
REPORT WILL BE MADE AVAILABE TO DEPARTMENT.

4. COOPERATION OF EMBASSY (ON BEHALF OF FDA INSPECTOR) REGARDING
ABOVE WILL BE APPRECIATED. KISSINGER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: TECHNICAL ASSISTANCE, SCIENTIFIC VISITS
Control Number: n/a
Copy: SINGLE
Draft Date: 05 JUN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE131573
Document Source: CORE
Document Unique ID: 00
Drafter: FDA/JRWEIEROTH M D
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750197-0358
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750676/aaaacrwv.tel
Line Count: 76
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 75 A3214, 75 STATE 103521
Review Action: RELEASED, APPROVED
Review Authority: greeneet
Review Comment: n/a
Review Content Flags:
Review Date: 24 MAR 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <24 MAR 2003 by PhilliR0>; APPROVED <30 JAN 2004 by greeneet>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA REPRESENTATIVE MAKING SITE VISIT
TAGS: OGEN, TBIO, JA, (WAYNE, CHARLES A)
To: TOKYO
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006